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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/725,843                       | 12/02/2003  | Hans Kurt Pingel     | 6207.520-US         | 3225             |
| 23650                            | 7590        | 01/15/2009           | EXAMINER            |                  |
| NOVO NORDISK, INC.               |             |                      | SWOPE, SHERIDAN     |                  |
| INTELLECTUAL PROPERTY DEPARTMENT |             |                      |                     |                  |
| 100 COLLEGE ROAD WEST            |             |                      | ART UNIT            | PAPER NUMBER     |
| PRINCETON, NJ 08540              |             |                      | 1652                |                  |
|                                  |             |                      |                     |                  |
|                                  |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                                  |             |                      | 01/15/2009          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nnipatent@novonordisk.com  
KSHL@novonordisk.com  
KISW@novonordisk.com

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/725,843             | PINGEL ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | SHERIDAN SWOPE         | 1652                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 November 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-6,8-15 and 17-24 is/are pending in the application.  
 4a) Of the above claim(s) 17-24 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-6 and 8-15 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

Applicants' response of November 3, 2008, to the Action of May 2, 2008, is acknowledged. It is acknowledged that Claims 1, 5, 8, and 15 have been amended. Claims 1-6, 8-15, and 17-24 are pending. Claims 17-24 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Claims 1-6 and 8-15 are hereby reconsidered.

### ***Priority***

Applicants have again requested that the present claims be accorded the benefit of DK PA 2000 01456, filed October 2, 2000. In support of said request, Applicants argue the following.

(A) "Applicants' position is that the present claims encompass the "broadest reasonable interpretation" as proposed by the Examiner. That is, a medium "lacking animal-derived components" means, as stated in the specification of DK PA 200 01456, "[a medium] that contains no protein or other component that was isolated from an animal tissue or an animal cell culture"."

(B) "Applicants do not intend that the claims should also encompass a medium [not] containing "recombinantly produced products that are naturally expressed in animals"."

These arguments are not found to be persuasive for the following reasons.

(A) Reply: Applicants' have mis-represented the Office's position. The prior action, stated:

"However, said statement [of DK PA 2000 01456] does not encompass the full scope of Claims 1-6 and 8-15 herein. Claims 1-6 and 8-15 herein recite a method using "medium lacking animal-derived components". The broadest reasonable interpretation of "medium lacking animal-derived components" encompasses medium lacking recombinantly produced components that are naturally expressed in animals. DK PA 2000 0145 fails to disclose a method using medium lacking animal-derived components, wherein the animal-derived components are recombinantly produced components that are naturally expressed in animals." (Examiner's emphasis).

(B) Reply: If Applicants do not intend that the claims should encompass use of a medium not containing recombinantly produced products that are naturally expressed in animals, the claims should be amended to clarify what is encompassed and what is not. For example, the phrase “medium lacking animal-derived components” could be amended to “medium that contains no protein or other component that was isolated from an animal tissue or an animal cell culture”, as recited in DK PA 2000 01456.

For these reasons and those explained in the prior actions, the priority date granted for the elected invention is October 2, 2001, the filing date of US 09/969,357, which discloses large-scale production of a Factor VII polypeptide using medium lacking animal-derived components.

***Claim Rejections - 35 USC § 101***

Provisional rejection of Claims 1-6, 8-11, and 15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-3, 5, 8, 10-13, and 15-17 of US Application 10/394,086, for the reasons explained in the prior actions, is maintained.

***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-6 and 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

Rejection of Claims 1-6 and 8-15 because, as explained in the prior action, the phrase “animal derived components” renders the claims indefinite, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. As

discussed above [under priority date], the ordinary meaning of the term encompasses components that are isolated from animal tissues or cells and that this meaning would be recognized by those of ordinary skill in the art. This argument is not found to be persuasive for the reasons explained above, under discussion of the priority date, and in the prior actions.

Rejection of Claims 1-6 and 8-15, because the phrase “said reference preparation comprises FactorVII produced in the presence of serum” renders the claim indefinite for the reasons explained in the prior action, is maintained. It is further noted that “reference preparation” is disclosed in the specification as being Factor VIII having altered glycosylation patterns (PGPub [0076]), which lends further confusion to the phrase. Applicants did not respond to this rejection.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

#### **Written Description**

Claims 1-6 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claims 1-6 and 8-15 introduce the limitation of using “at least 500 L of culture medium”. The specification fails to describe said limitation and, thus, Claims 1-6 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Claims 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claim 5 introduces the limitation of cells “adapted to grow in macroporous carrier suspension culture prior to being inoculated into the seed vessel”. The specification fails to describe said limitation and, thus, Claim 5 is rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 1-3, 6, 8-11, and 15 under 35 U.S.C. 102(b) as being anticipated by Reiter et al, 2000, for the reasons explained in the prior action, is maintained. It is noted that Reiter et al teaches the use of “batch culture on a 1,000 liter scale” (col 4, parg 8); which anticipates the claims as amended (see Claim 1). In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(C) Reiter et al. contains no specific disclosure of production of Factor VII in CHO cells using a serum-free/animal component-free medium. Factor VII is merely one of a long list of proteins cited as possible candidates for production using such a system; is cited only a single time in the patent specification (Reiter et al., column 4, line 44); and is not even included in the subset of so-called "particularly preferred" embodiments (Reiter et al., column 4, lines 47-51).

Contrary to the Examiner's implication, Example 1 refers to von Willebrand's Factor, not Factor VII, and, notably, Example 5 refers to Factor VIII, not Factor VII.

(D) Factor VII and Factor VIII are very different proteins and are not interchangeable; the same applies to Factor VII and von Willebrand's Factor. Reiter et al. thus provides no guidance relating to production of Factor VII; thus, it would be impossible to even contemplate comparing a Factor VII preparation produced by a (non-existent) method of Reiter with one produced by the methods of the present invention.

These arguments are not found to be persuasive for the following reasons.

(C) Reply: It is acknowledged that the methods disclosed in the Examples do not use Factor VII; and, that Examples 1 and 6 specifically use von Willebrand's Factor and Factor VIII, respectively. Nonetheless, the skilled artisan would recognize that Reiter et al teaches that Factor VII can be used in said methods. MPEP 2123 states:

I. PATENTS ARE RELEVANT AS PRIOR ART FOR ALL THEY CONTAIN

"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain."

and

II. NONPREFERRED AND ALTERNATIVE EMBODIMENTS CONSTITUTE PRIOR ART

"Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments."... "Furthermore, '[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed..'"

(D) Reply: It is acknowledged that Factor VII is different and not interchangeable with Factor VIII and Willebrand's Factor. Nonetheless, for the reasons explained above and in the prior actions, the skilled artisan would recognize that Reiter et al teaches that Factor VII can be used in their disclosed methods.

For these reasons and those explained in the prior actions, rejection of Claims 1-3, 6, 8-11, and 15 under 35 U.S.C. 102(b) as being anticipated by Reiter et al, 2000, is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claims 4 and 11 as well as Claims 12-14 under 35 U.S.C. 103(a) as being unpatentable over Reiter et al, 2000 in view of Chen et al, 1998, for the reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the same arguments stated above, (C)-(D), regarding Reiter et al, 2000. Said arguments are not found to be persuasive for the reasons explained above.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652